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Arlington, VA 22202-4501

Attention: Mr. Matthew Khan, Pesticide Re-Evaluation Division

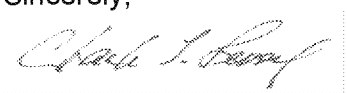
Subject: **Thiamethoxam Registration Review**
60-Day Comments by Syngenta in Response to the Thiamethoxam Registration Proposed Interim Decision Posted 2/3/20
Case Number: 7614
Docket Number: EPA-HQ-OPP-2011-0581

Dear Mr. Khan:

On January 30th, 2020, the EPA published a Notice in the Federal Register announcing the availability of the Proposed Interim Registration Decision for Thiamethoxam (case number 7614). With this notice, the Agency opened the 60-day public comment period. Syngenta reviewed the associated documents posted to the docket, however, we did not have time to review the Supporting Documents (DER) that were posted on 4/29/20.The Agency posted 32 data evaluation records (DERs) for studies submitted to support the Bee, Aquatic and Non-Pollinator Terrestrial Risk Assessments to the docket. Syngenta did not have sufficient time to thoroughly review all of the DERs prior to the end of the public comment period (05/04/20). It would be helpful for the Agency to provide the DERs closer to the time the risk assessments are posted to the docket so they can be properly evaluated to better understand the quality and source of data used in the assessments and inform our comments. Syngenta is providing the enclosed comments with the goal towards insuring accuracy, clarity and transparency.

Syngenta appreciates the opportunity to provide comments to the Thiamethoxam docket for Agency consideration. If you have any questions or comments regarding this response, please contact me at 336-632-2446 or by e-mail at Charles.Levey@syngenta.com.

Sincerely,



Charles Levey
Federal Team Lead, Insecticides
Regulatory Affairs Department
Syngenta Crop Protection, LLC

Thiamethoxam: Proposed Interim Registration Review Decision, Dated January 22, 2020, *(EPA- EPA-HQ-OPP-2011-0581)*

	EPA statement
Page 10, Paragraph 4	EPA Response: The agency agrees that the seed treatment exposure calculations using application rates from EPA Reg. # 100-941 should also include the gallons per day restriction noted on the label. However, the agency identified labels (e.g., EPA Reg. # 100-1184) that did not include a gallons per day restriction. Additionally, the agency determined risks of concern for seed crop uses (specifically field, pop and sweet corn) identified on these labels, even when the maximum personal protection equipment (PPE; double-layer clothing and gloves and a respirator) were considered. As a result, the agency is proposing a requirement that commercial facilities perform thiamethoxam corn seed treatments only in closed loading systems. For more information, please refer to Section III.A.1 and IV.A.3 of this PID, as well as Thiamethoxam. Revised Response to Public Comments on the Thiamethoxam Human Health Draft Risk Assessment for Registration Review, available in the thiamethoxam docket.

Syngenta Comment: Syngenta thanks the agency for incorporating the volumetric restrictions currently on the Cruiser 5FS (EPA Reg. #100-941) label and acknowledging that following these volumetric restrictions would lead to no risks of concern (this label has a 38 gal restriction for open system and a 215 gal restriction for closed system). With regards to other labels with corn (field, pop, and sweet) seed treatment (EPA Reg. #s 100-1405, 100-1321, 100-1353), these labels all have a closed system restriction and hence, there should be no occupational risks of concern. Three other thiamethoxam-containing Syngenta products labeled for use on corn seed, EPA Reg. #s 100-1184,100-1399, and 100-1208, have recently been canceled. Syngenta believes it has met this proposed requirement for all currently registered Syngenta thiamethoxam end-use products.

	EPA statement
Page 23, Paragraph 4	The agency also received comments from Syngenta that facilitated refinements to some of the risk calculations presented in the draft human health risk assessment. After incorporating the volumetric use restriction currently on the label for EPA Reg. #100-941 (Cruiser 5FS) limiting the gallons of product that may be handled per 8-hour day, EPA found that there are no risks of concern (i.e., MOEs are above the LOC) for the seed crops listed on this label (including field corn, popcorn, sweet corn, cotton, flax, mustard, rice, safflower, and sunflower) for all seed treatment activities. However, other labels exist with corn (field, pop, and sweet) seed treatment which do not include volumetric use restrictions, and occupational risks for these labels remain of concern. Syngenta also provided

Syngenta Comment: Syngenta thanks the agency for incorporating the volumetric restrictions currently on the Cruiser 5FS (EPA Reg. #100-941) label and acknowledging that following these volumetric restrictions would lead to no risks of concern (this label has a 38 gal restriction for open system and a 215 gal restriction for closed system). With regards to other labels with corn (field, pop, and sweet) seed treatment (EPA Reg. #s 100-1405, 100-1321, 100-1353), these labels all have a closed system restriction and hence, there should be no occupational risks of concern. Three other thiamethoxam-containing Syngenta products labeled for use on corn seed, EPA Reg. #s 100-1184,100-1399, and 100-1208, have recently been canceled by Syngenta.

	EPA statement
Page 50, Paragraph 3	EPA is proposing to mitigate these risks through the requirement of additional Personal Protection Equipment (PPE) such as gloves, respirators, or requiring closed loading systems for seed treatment on labels.

Syngenta Comment: For the reasons provided in our comments to other EPA statements (Page 10, paragraph 4; page 23, paragraph 4; page 56, paragraph 1-3) herein, Syngenta believes that this restriction does not apply to Syngenta thiamethoxam seed treatment products labeled for use on corn seed.

	EPA statement
Page 56, Paragraph 1-3	4. Closed System Requirement for Thiamethoxam Corn Seed Treatments As noted in Section III.A.1. of this PID, potential risks of concern have been identified for occupational handlers from the use of thiamethoxam for corn seed treatments in commercial facilities. Even with maximum PPE (double layer of clothing, gloves, and an elastomeric half-mask respirator) required for these uses, certain field, pop, and sweet corn seed treatment scenarios still have MOEs of concern for certain activities, ranging from 13 – 43. These MOEs are well below the agency's level of concern of 100. To protect the health of workers involved in commercial seed treatments of corn using thiamethoxam, EPA is therefore proposing that the use of a closed loading system be required for all thiamethoxam corn seed treatments conducted in commercial facilities. With the addition of a closed loading system, EPA would no longer expect any potential risks of concern to human health for corn seed treatments of thiamethoxam in commercial facilities. EPA is proposing that all thiamethoxam products registered for corn seed treatment uses must include the following statement on labels: • "Must be applied by closed system seed treatment application processes when applied in commercial seed treatment facilities." EPA identified no risk estimates of concern for corn seed treatment uses of thiamethoxam in the case of on-farm seed treatments, and mitigation is therefore not being proposed for that use scenario.

	The closed system requirement being proposed in this PID is for commercial facilities only.

Syngenta Comment: Previously in the Thiamethoxam: Proposed Interim Registration Review document (page 23, paragraph 4), the agency incorporated the volumetric restrictions currently on the Cruiser 5FS (EPA Reg. #100-941) label and acknowledged that following these volumetric restrictions would lead to no risks of concern (this label has a 38 gal restriction for open system and a 215 gal restriction for closed system). With regards to other products with corn (field, pop, and sweet) seed treatment (EPA Reg. #s 100-1405, 100-1321, 100-1353), these labels all have a closed system restriction and hence, there should be no occupational risks of concern. Three other thiamethoxam-containing Syngenta products labeled for use on corn seed, EPA Reg. #s 100-1184,100-1399, and 100-1208, have recently been canceled. Syngenta believes it has met this proposed requirement for all current Syngenta thiamethoxam end-use products.

	EPA statement
Page 64, Table 6. Proposed Crop Stage-based Application Restrictions for Thiamethoxam	Fruiting Vegetables: The agency is proposing a crop stage restriction for both foliar and soil labels, to not apply after the appearance of the initial flower buds until flowering is complete and all petals have fallen off. Additionally, for tomatoes, peppers, chili peppers and okra only, EPA is also proposing to not apply after 5 days after planting or transplanting regardless of application method.

Syngenta Comment: The proposed mitigation for tomatoes, peppers, chili peppers and okra give the impression that no applications, including foliar applications, can be made 5 days after planting or transplanting. However, Syngenta believes that the available residue data supports foliar applications to fruiting vegetables if applications are made prior to the appearance of flower buds. We assume that the intention of the term "regardless of application method" is in reference to the various soil application methods (e.g., drench, chemigation, etc.) which should be more clearly separated from the proposed mitigation for foliar applications.

	EPA statement
Page 79, Row 1, Column 6 of Table 2	Require closed loading for seed treatment

Syngenta Comment: For the reasons provided in our comments to other EPA statements (Page 10, paragraph 4; page 23, paragraph 4; page 56, paragraph 1-3) herein, Syngenta believes that this restriction does not apply to Syngenta thiamethoxam seed treatment products labeled for use on corn seed.

	EPA statement		
Page 96, Row 2 of Table	Seed treatments to corn	"Must be applied by closed system seed treatment application processes in a commercial seed treatment facility."	Directions for Use

Syngenta Comment: For the reasons provided in our comments to other EPA statements (Page 10, paragraph 4; page 23, paragraph 4; page 56, paragraph 1-3) herein, Syngenta believes that this restriction does not apply to Syngenta thiamethoxam seed treatment products labeled for use on corn seed.

Thiamethoxam: Response to Public Comments on Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam *(EPA- EPA-HQ-OPP-2011-0581-0371)*

	EPA statement
Page 32, Table 1.3. Acute and chronic toxicity endpoints used for assessing risk to bees from exposure to clothianidin and thiamethoxam.	Thiamethoxam Adult Acute Oral Toxicity 48-hr LD50 = 0.0038 µg c.e./bee; MRID 49005702

Syngenta Comment: The adult acute oral honey bee toxicity study that Syngenta submitted to the Agency (MRID 44714927) resulted in a 48-hr LD50 = 0.005 ug ai/bee (0.004 ug c.e./bee). In review of the data evaluation record (DER) for MRID49005702 (EAD DER Number 2352281), it is mentioned that the study **partly** followed OECD 213 and 214 guidelines. Several guideline deviations were noted including 1) No LD50 value was determined; 2) No reference item treatment was included in this test; 3) The relative humidity fell outside the recommended range of 50-70%. Syngenta believes that data from a valid study that fully follows OECD guidelines (MRID 44714927) are more robust to establish the 48-hr adult acute oral LD50 for thiamethoxam than data from MRID 49005702. The DER also indicated that the endpoints from MRID 49005702 were 96-hr LC50 values rather than 48-hr LD50 value as indicated in the risk assessment. This is important to note considering additional morality was observed between the 48- and 96-hr assessment times which would influence the estimate of the LC/LD50 value and it is uncertain if the reviewer was unable to calculate a dose based on the available data and resorted to a concentration-based endpoint. While the difference in the endpoints reported are not likely to impact the screening level risk assessment, Syngenta advocates that the 48-hr LD50 from MRID 44714927 be used because of the study deviations, use of data outside the context of the study and longer study duration of MRID49005702.

	EPA statement
Page 32, Table 1.3. Acute and chronic toxicity endpoints used for assessing risk to bees from exposure to clothianidin and thiamethoxam.	Thiamethoxam Larval Acute (single dose) LD50 = >0.03 µg c.e./larva/day; MRID 50096607

Syngenta Comment: The reported value of >0.03 µg c.e./larva/day appears to be an error. The cited study (MRID 50096607) was a 22-day chronic larval study and the 8-day LD50 from that study was reported as >0.501 µg ai/larva development period (>0.429 µg c.e./larva). EPA's current practice of estimating daily dose is to divide the endpoint by 4, the number of days the larvae are exposed to the test diet. The value of >0.501 µg ai/larva divided by 4 results in >0.125 µg ai/larva/day (>0.107 µg c.e./larva/day). While the difference in the endpoints reported are not likely to impact the screening level risk assessment, we believe the value is in error and should be corrected. Further, it should be noted that endpoints from EPA's risk assessments are often used by other regulatory authorities as cited and not directly from the source studies.

	EPA statement
Page 64, Last paragraph	• Concentrations of residues of concern in are approximately an order of magnitude more than residues in nectar;

Syngenta Comment: Syngenta assumes that the above sentence should read "Concentrations of residues of concern in *pollen* are approximately an order of magnitude more than residues in nectar.

	EPA statement
Page 88, Table 3.13. Summary of the maximum single value and maximum mean residue concentration in pollen and/or nectar from the residue studies for clothianidin and thiamethoxam.	Thiamethoxam (c.e. ng/g) Applications Method: Foliar Crop (MRID): Soybean (MRID 50265503) Max TR conc. in pollen = 545[b] Max TR conc. In nectar = 44.3 Max mean TR conc. in pollen = 486[b] Max mean TR conc. in nectar = 42.5 b = no pollen data. Whole flower and anther data available. Highest values presented from whole flower data.

Syngenta Comment: It is uncertain why the Agency used whole flower data to represent pollen concentrations when anther data are available particularly when the Agency has mentioned in other sections of the risk assessment that anthers are used "as a surrogate for pollen where those data are available and pollen data alone are not available." In addition, the nectar values for soybean are reported incorrectly in this table and Table 5.6. The correct nectar values for foliar applications are lower (max = 9.7 c.e. ng/g). In the Tier II assessment section, the correct nectar values appear to be used in Figures 5.26 and 5.27 with the risk characterization indicating low risk to bees. Similar to the previous comments, we believe the values are in error and should be corrected. Further, it is important to have correct values within the assessment as they are often reported as cited by other authorities and stakeholders and may lead to erroneous conclusions.

	EPA statement
Page 91, Last paragraph	When comparing the available toxicity data for honeybees, the acute adult endpoints overlap for clothianidin and thiamethoxam. The adult chronic endpoints are within a factor of 6 of each other, suggesting that the chronic toxicity of these chemicals to adults is similar.
Page 94, Last paragraph	When considering the effects observed in the 2014 sucrose CFSs compared to those conducted in 2016, the endpoints for the same chemical are within a factor of 2. Similarly, when comparing the clothianidin and the thiamethoxam endpoints from the same year, the endpoints are less than a factor of 2 apart. This suggests that the toxicities of clothianidin and thiamethoxam to honeybee colonies are similar.
Page 96, First paragraph	When considering the four colony level studies, decreased number of adults were observed in the range of 34-75 ng c.e./g. This is consistent (i.e., within a factor of 4) with the clothianidin chronic adult toxicity study where significant (12%) mortality was observed at 17.7 ng c.e./g. The thiamethoxam chronic adult toxicity study reported significant (70%) mortality at 181 ng c.e./g, which within a factor of 5 of the colony level endpoints; although it is less conservative.

Syngenta Comment: In several places in the bee risk assessment, the Agency states that clothianidin and thiamethoxam endpoints are within a factor of "x" of each other which suggests that the toxicity of clothianidin and thiamethoxam are similar. However, the Agency provides no reference on how far apart endpoints need to be before they are considered significantly different. This gives the impression that the Agency is trying to justify their conclusion that the thiamethoxam and clothianidin endpoints are similar without providing any statistical justification for this conclusion.

Syngenta's position is that the chronic toxicity of thiamethoxam to honey bees is ***not*** similar to clothianidin as confirmed by the laboratory toxicity and colony feeding studies.

	EPA statement
Page 96, First paragraph	When considering the four colony level studies, decreased number of adults were observed in the range of 34-75 ng c.e./g. This is consistent (i.e., within a factor of 4) with the clothianidin chronic adult toxicity study where significant (12%) mortality was observed at 17.7 ng c.e./g. The thiamethoxam chronic adult toxicity study reported significant (70%) mortality at 181 ng c.e./g, which within a factor of 5 of the colony level endpoints; although it is less conservative. Effects to stored pollen, and brood (eggs, larvae and pupae) were also observed at 34-75 ng c.e./g. A decline in brood (eggs, larvae and pupae) were all observed at the same time points (CCAs) as adult declines. The Tier I toxicity data for larvae exposed to thiamethoxam (LOAEC = 200 ng c.e./g) suggests that there could be direct effects to larvae; however, this may not be the case based on the clothianidin study (LOAEC = 1500 ng c.e./g). Taken together, these studies suggest that direct toxicity to brood may not be the cause of observed effects in the colony studies. Decreased number of adult worker bees can lead to insufficient number of nurse bees to tend brood and forage for pollen. Hives stressed due to insufficient number of adult workers and food have been observed with increased brood loss (Winston 1987).

Syngenta Comment: The Agency is suggesting that the colony level effects observed at the LOEC (i.e., reduction in brood production and pollen stores) in the colony feeding studies for both clothianidin and thiamethoxam was a result of direct mortality in adult bees which led to insufficient number of nurse bees to tend to brood and insufficient number of foragers to forage for pollen. However, the number of adult bees were only significantly different in the highest treatment concentration in the thiamethoxam colony feeding study and for only the first study. In addition, there was no visual indication of adult bee mortality (i.e., bee kill) in the thiamethoxam studies. A more plausible explanation is that the significant reduction in brood for both the thiamethoxam and clothianidin colony feeding studies was directly related to reduced pollen stores and most likely a result of reduced foraging rather than mortality of adult honey bees. This hypothesis is supported by studies demonstrating reduced foraging (i.e., "homing") efficiency of adult honey bees exposed to thiamethoxam via sucrose at similar concentrations to the colony feeding study LOEC of 50 ppb (Fourrier 2017 and Henry 2012).

References:

Fourrier et al., 2017. The homing flight ring test: method for the assessment of sublethal doses of plant protection products on the honeybee in field conditions. Hazards of pesticides to bees - 13th international symposium of the ICP-PR Bee protection group, October 18 – 20 2017, Valencia (Spain)

Henry M, Beguin M, Requier F, Rollin O, Odoux JF, Aupinel P, Aptel J, Tchamitchian S, Decourtye (2012) A common pesticide decreases foraging success and survival in honeybees. Science 336(6079):348-350

	EPA statement
Page 111	Ground applications were modelled using AgDRIFT in Tier I ground mode with a range of ground application rates and the default droplet size (very fine to fine) with a high boom height. Results indicate that contact RQ values exceed the acute risk LOC from 33-300 ft. beyond the treated field. Aerial applications were modelled using AgDRIFT in Tier I Aerial mode with default droplet size (fine to medium). Results indicate that contact RQ values exceed the acute risk LOC from 120 to 630 ft. beyond the treated field. Acute and chronic Tier I dietary-based RQ values exceed their respective LOCs for more than 1000 ft. from the edge of the treated field for both ground and aerial applications. Chronic exceedances are based on repeated exposures at the same concentration and do not take into account the degradation of the chemical. Consequently, without considering how long residues remain to trigger the chronic risk LOC, there is some uncertainty regarding the chronic of off-field risks. Additionally, the AgDrift model assumes that there is no interception by a crop canopy and that winds are unidirectional and constant Results are presented below in Table 5-4.

Syngenta Comment: Syngenta would like to make the Agency aware of a field drift study conducted with thiamethoxam (Perine 2018; MRID 51128201). In this study, Actara® 25WG was applied at 0.086 lbs ai/A, the maximum single application rate for foliar uses, via tractor boom to a mowed stubble plot. Three nozzle types were evaluated, TeeJet XR11003, DG11004 and AIXr11002. Stainless steel plate sampling devices were located downwind, perpendicular to the spray swath at distances ranging between 12.5 and 400 ft from the edge of the treated field. Stainless steel rod and filter paper samples were also collected within these distances. Mean measured thiamethoxam residues on stainless steel sampling devices ranged from 0.00084 lbs ai/A at 12.5 ft downwind from the edge of field to 0.0000046 lbs ai/A at 400 ft downwind. Measured drift rates from the AIXR11002 nozzle were lower than drift rates from the XR11003 and DG11004 nozzles which were similar.

The table below compares the distances for RQs to exceed tier 1 LOCs using AgDRIFT estimates for ground application as stated in the EPA's Final Bee Risk Assessment versus the measured values from the thiamethoxam field drift study.

Chemical	Application Rate (lbs ai/A)	Acute contact distance (ft)		Acute oral distance (ft)		Chronic distance (ft)	
		AgDRIFT estimate	Measured	AgDRIFT estimate	Measured	AgDRIFT estimate	Measured
Thiamethoxam	0.086	72	<12.5 (0.75)*	>1000	113**	>1000	91**

* Extrapolated estimate using equation from linear mixed-effects modeling of spray drift curve for XR11003 nozzle
** Calculated value based on equation from linear mixed-effects modeling of spray drift curve for XR11003 nozzle

As indicated in the table, using measured values compared to estimated AgDRIFT values greatly reduces the perception of off-field risk at extended distances from the edge of field. While AgDRIFT can be used to estimate off-field drift from ground and aerial applications in a tier 1 screening-level assessment, Syngenta requests the Agency consider measured drift data from

field studies when available to refine the ground application scenario. In addition, No Observed Adverse Effects Rates (NOAERs) from tier 2 semi-field studies could be used to directly compare with measured drift rates to further refine the off-field assessment. In a semi-field tunnel study assessing the effects of thiamethoxam drift rates on honey bee colonies, rates of 5 and 1 g ai/ha (0.0045 and 0.00089 lbs ai/A, respectively) were applied to blooming *Phacelia* either during or after daily bee flight (Nengel 1998; MRID 50281204). Mortality, foraging activity, colony condition and development of brood were assessed before and after treatment. The colony NOAER was determined to be 5 g ai/ha (0.0045 lbs ai/A). Based on the equation used above, the predicted (extrapolated) no effect distance for protecting honey bee colonies would be 0.35 ft from the edge of field indicating minimal off-field risk to honey bee colonies from ground spray applications of thiamethoxam.

	EPA statement
Page 153	Because thiamethoxam transforms to clothianidin within plants, the total residue is represented as both thiamethoxam and clothianidin. In the available thiamethoxam soil treatment residue studies for cucurbits, both chemicals occurred in nectar and pollen. In nectar, clothianidin represented an average of 22% of the residues in muskmelon, 29% in pumpkin and 18% in squash (MRID 50265501). In pollen, clothianidin represented 48% of the residue (on average) in muskmelon and pumpkin and 33% of the residue in squash. In another study with cucumber, residues in nectar ranged 11-33% and 14-20% in pollen (MRID 49550801). This indicates that both the thiamethoxam and clothianidin CFS endpoints should be considered in evaluating the risk of cucurbits.

Syngenta Comment: The Agency indicates that because both clothianidin and thiamethoxam were detected in nectar and pollen and therefore, both CFS endpoints should be considered for evaluating risk of cucurbits. However as stated in the risk assessment, residues of clothianidin were on average never higher than 29% in nectar or 48% in pollen; the majority of the residue was thiamethoxam in both matrices. As indicated for the seed treatment use of thiamethoxam on cucurbits on page 126 of the assessment, "*Available residue studies from thiamethoxam seed treatments on corn, cotton, soybean and canola (summarized in Attachment 4) indicate that the composition of thiamethoxam in pollen and nectar of treated crops ranges 11-98% of the residues, with the majority of studies showing that thiamethoxam is the predominant component of the total residue (Table 5-16). This suggests that more weight should be placed on the thiamethoxam CFS endpoints when evaluating risk.*" In Table 5-16, the mean percent of thiamethoxam in soybean nectar from 8 samples was 69 which would indicate that 31% would be clothianidin. Likewise, for corn pollen, in 133 samples analyzed the mean percent thiamethoxam was 59 indicating 41% would be clothianidin. Syngenta believes that the percentages of thiamethoxam and clothianidin in nectar and pollen samples from soil uses on cucurbits are in line with the seed treatment data and therefore, more weight should be placed on the thiamethoxam endpoint when evaluating risk. However as stated on page 154 of the assessment, "*Overall, the available information suggests potential for risks of concerns for bees from soil applications of thiamethoxam to cucurbit crops based on exceedances of the clothianidin CFS NOAEC endpoints".* As there were no nectar equivalent residue levels above the NOEC from the thiamethoxam CFS, Syngenta believes there is acceptable risk from soil applications of thiamethoxam to cucurbits and requests the Agency be consistent with data interpretation across crops and uses when characterizing potential risk for crops which have both clothianidin and thiamethoxam residues in nectar and/or pollen.

As mentioned previously, Syngenta's position is that the chronic toxicity of clothianidin to honey bees is not similar to thiamethoxam as confirmed by the laboratory toxicity and colony feeding studies. As opposed to using Agency judgement on use and weight of data from either the clothianidin or thiamethoxam CFS based on the percentage of residues of each in pollen and/or nectar from crops, the Agency could use a toxic unit approach (see Syngenta's response to the 2017 Preliminary Bee Risk Assessment to Support the Reregistration Review of Clothianidin and Thiamethoxam posted to the docket EPA-HQ-OPP-2011-0581). This would provide a quantitative method to scale measured concentrations of clothianidin and thiamethoxam in pollen and/or nectar to their inherent effect concentrations from the CFSs resulting in a summation of overall effects.